



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,933	09/12/2003	William R. Fitz	FIT-10302/29	7041

7590 09/26/2005

JOHN G. POSA
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, P.C.
280 N. Old Woodward Ave. Suite 400
Birmingham, MI 48009-5394

EXAMINER

PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
----------	--------------

3739

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/660,933	Applicant(s) FITZ, WILLIAM R.	
	Examiner Michael Peffley	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10 is/are rejected.
7) ☒ Claim(s) 1 and 8 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 12 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/12/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the cannula having a spoke-like cross section as set forth in claim 5 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 1 and 8 are objected to because of the following informalities: claim 1 should recite "a plurality" in line 3, and claim 8 should apparently read "wherein there is at least one side port" in line 2. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by cannula that are generally spoke-like in cross section. It is noted that there is no depiction of such a limitation in the figures, and the specification only makes brief mention of this feature without explaining what is meant. If Figure 3 is representative of a "spoke-like" cannula, then it is noted that there is no disclosure of providing a plurality of "spoke-like" cannula as recited in the claims. Rather, Figure 3 appears to show a single cannula (302) having a plurality of compartments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough (6,080,150).

Gough provides a device comprising a flexible introducer (12) having a plurality of elongated, co-extensive cannula (18). An electrode (16) is located in each electrode, and each electrode is insulated by the cannula. The electrode is movable within the cannula to vary the length of the exposed electrode. The electrodes include sharpened tips (see Figures) and are constructed from a shape-memory alloy (col. 4, lines 44-50). The cannula are generally parallel and may lie in the same plane (see cross section Figure 6C where two of the cannula would define a plane). As asserted previously, it is not clear what is meant by a cannula having a "spoke-like" cross section, but the cross-section of Figure 6C is deemed to meet such a limitation in that each cannula may be considered a "spoke". Gough also provide for the lateral deployment of the electrodes (Figures 6A and 6B) as well as ports in the electrode for delivering an agent (col. 7, lines 58+). The discussion regarding the deployment of the electrodes indicates that they are deployed in unison (see, for example, col. 5, lines 12-15). The Gough device is deemed inherently capable of being used in neurotomy procedures.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gough et al (5,672,173).

The Gough et al system is substantially identical to the Gough ('150) device and includes an introducer (14) having a plurality of electrodes (16) slidably received in a plurality of cannula (18). The electrodes are insulated by the cannula, and the

Art Unit: 3739

electrodes are sharpened and may be deployed laterally (Figure 3). The electrodes are made from a shape memory alloy (col. 4, lines 58-65). The disclosed method indicates that the electrodes may be deployed singularly or in unison (col. 6, lines 25-31). Again, the device is deemed inherently capable of being used in neurotomy procedures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough ('150) in view of the teachings of Edwards et al (5,536,267) and Edwards et al (5,370,675).

The Edwards et al (267) and Edwards et al ('675) devices are very much like the Gough device in that they include a plurality of electrodes each slidably located within a cannula (i.e. insulation) and all located within an introducer. In particular, Edwards et al ('267) disclose that the electrodes may be simultaneously deployed (col. 7, lines 60-65). Edwards et al ('675) disclose an analogous device with means to individually extend the electrodes (see Figure 26). The examiner maintains that to have provided either deployment mechanism would have been an alternative design consideration for one of ordinary skill in the art.

To have provided the Gough device with a deployment means for deploying the electrodes either singularly or in unison is deemed to be an obvious design

Art Unit: 3739

consideration for one of ordinary skill in the art, particularly since Edwards et al ('267) and Edwards et al ('675) teach that either type of deployment mechanism is known in analogous devices.

Conclusion

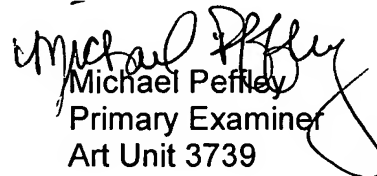
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schaefer et al (6,638,277) and LeVeen et al (5,868,740) disclose other devices comprising introducers having a plurality of electrodes deployable therefrom. Jones et al (5,849,011) disclose another apparatus having two cannula located within an introducer, each cannula housing an insulated electrode for deployment into tissue.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Michael Perley
Primary Examiner
Art Unit 3739

mp
September 22, 2005